K043015

AUG 15 2005

510(k) Summary of safety and effectiveness

1. General information

Establishment:	3L Medical Products Group Co., Ltd.
Registration number:	3004133236
Contact Person:	George Su Crosslinks International 1800 Century Park East, Suite 600 Los Angeles, CA 90067 USA
Common Name:	Surgical drape
Classification Name:	Surgical drape and drape accessories
Predicate Device:	3M™ Surgical Drape
Product Code:	KKX
510(K) Number:	K031287

2. Device Description

3L® Surgical Drapes are made from PE or PU sheets with adhesive strips, sterilized or nonsterilized. They provide an isolating barrier during surgical procedures to cover the patients and stops fluid strike-through.

3. Substantial Equivalence

3L® Surgical Drapes are generally identical to 3M™ Surgical Drapes in design, material, specifications and intended use

4. Description of Testing

Physical and biological tests were performed in accordance with industry recognized test methods,.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2005

3L Medical Products Company, Limited
C/O Mr. George Su
Crosslinks International Incorporated
1800 Century Park East, Suite 600
Los Angeles, California 90067

Re: K043015
Trade/Device Name: 3L® Surgical Drapes
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape
Regulatory Class: II
Product Code: KKX
Dated: July 28, 2005
Received: July 28, 2005

Dear Mr. Su:

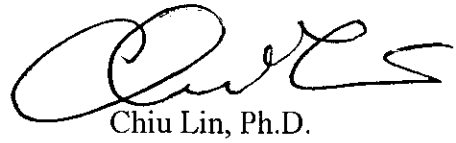
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043015

Device Name: 3L® Surgical Drape

Indications For Use:

3L® Surgical Drapes described in this submission are intended to be used to provide an isolating barrier during surgical procedures. The drapes cover the patient and are made of plastic with a protective film that stops fluid strike-through.

The drapes submitted provide an isolator as a vertical barrier to keep the C-arm from the surgical field during hip/femur fracture or trauma procedures, or create a isolating barrier during orthopedic procedures, or provide secure adhesion on drapes for general use, or meet surgical minor procedural needs, or give a sterile surface all of the way to the wound.

Prescription Use ___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K043015